UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,549	01/11/2002	Willy Deleersnijder	01975.0032	8772

7590 11/20/2003

Finnegan Henderson Farabow
Garrett & Dunner
1300 I Street NW
Washington, DC 20005

EXAMINER	
GUCKER, STEPHEN	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/030,549	Delensnyder et al.
Examiner	**Group Art Unit**
Stephen Gucker	1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 7/16/03.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-33 is/are pending in the application.

Of the above claim(s) 10, 13-22, + 29 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-9, 11-12, 23, + 25-33 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3, 7, + 8

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Response to Amendment

1. Applicant's election with traverse of Group I, claims 1-9, 11-12, 23 (in part) and 25, in Paper No. 13, filed 6/6/03 is acknowledged. The traversal is on the ground(s) that the inventions encompassed by the various Groups do not constitute a search burden because the claims in these different groups would encompass the same search. This is not found persuasive because separate databases would have to be searched regarding nucleic acids, protein sequences encoded by the nucleic acids, and antibodies that bind to the encoded sequences, in addition to a wide open search for every possible chemical agonist or antagonist. This indeed constitutes a serious search burden. The Examiner also disagrees with Applicant's assessment that the protein of Group II and the antibody of Group III cannot be made without the nucleic acid of Group I. The protein can be isolated from its natural source. Antibodies can be made to this isolated protein or epitope fragments can be produced using peptide synthesis and then used as immunogens to produce antibodies to the whole protein. Neither of these methods would use the nucleic acid of Group I.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicants have made an election with traverse. The petition decision filed 2/21/03 states that: **"Failure to make an election without traverse will void the special status accorded in this decision."**

3. Claims 10, 13-22, and 24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made with traverse in Paper No. 13, filed 6/4/03.

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-9, 11-12, 23 (in part), 25, and 26-33 (in part - limited to polynucleotides by original election) are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a well-established utility or a disclosed specific and substantial credible utility. The instant claims are drawn to multiple genuses of isolated nucleic acids that share 80% or 90% sequence identity to SEQ ID NO:1 or a nucleotide sequence encoding SEQ ID NO:2 (a receptor protein called IGS1), the complementary sequences thereof, or various expression systems (i.e. vectors), host cells, or methods of expressing the proteins encoded by the multiple genuses of isolated nucleic acids. The underlying asserted utility for the encoding nucleic acid sequences for IGS1 is that it is a member of the G-protein coupled receptor (GPCR) superfamily, and therefore has utility for disease diagnosis, therapy, drug screening, genetic analysis for mutations for inherited disorders, and as a chromosomal marker.

First, there is no well-established utility for the instant nucleic acids or the encoded receptor protein. Applicants have not taught what the instant receptor protein is a receptor for, therefore, no known ligand exists that binds to and activates the encoded instant protein. Likewise, no known ligand exists that binds to and inhibits the activation of the encoded instant protein. Therefore, it is completely unknown what biological processes the instant protein or its underlying encoding nucleic acids are associated with or involved in. It is not known if the receptor when activated by its endogenous ligand produces a stimulatory or inhibitory signal to the cell that the receptor is a part of. In fact, the nature of the signal that the instant receptor transduces when its unknown ligand binds to it is also unknown. Because the endogenous or exogenous (i.e. drug) ligand that would bind to the instant receptor has not yet been discovered, the instant receptor is called an "orphan receptor" by those of ordinary skill in the art. The instant receptor and its encoding nucleic acids have no well-established utility because no known compound exists which binds to the receptor and produces or inhibits its biological function, the specific biological processes in which the receptor participates in are unknown, and the second messenger or any other known signal transduction means by which this receptor could operate has not been demonstrated in any specific or substantial way by the teachings of the instant disclosure.

As stated therein, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance. This is a protein whose cDNA has been isolated

because of its similarity to known proteins. There is little doubt that, after complete characterization, this protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to nucleic acids of as yet undetermined function or biological significance. There is absolutely no evidence of record or any line of reasoning that would support a conclusion that the nucleotides of the instant application can be used for diagnosis, prevention and treatment of diseases or disorders as stated at pages 3-4 of the specification. Until

some actual and specific significance can be attributed to the protein identified in the specification as IGS1, or the gene encoding it, the instant invention is incomplete. The DNA of the instant invention and the protein encoded thereby are compounds which share some structural similarity to G-protein coupled receptors (GPCR). Because the various members of the GPCR protein superfamily have different sites of action and different biological effects, it is not clear if the protein of the instant application would be a receptor for a growth factor, an inhibitor of cell proliferation, a binding protein, a hormone, a cytokine, a lymphokine, a neurotransmitter, or even possibly a transcription factor. In the absence of a knowledge of the ligand to which IGS1 binds, or the biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in any of the disclosed methods would clearly be using it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a specific and substantial "real world" use for IGS1, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. §101 as being useful.

Any unique nucleic acid sequence can serve as a chromosomal marker. Therefore, the instant invention does not have a specific utility as a chromosomal marker that is not shared with any and every other nucleic acid sequence that encodes a GPCR.

7. Claims 1-9, 11-12, 23 (in part), 25, and 26-33 (in part - limited to polynucleotides) also are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the

reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

November 14, 2003

Gary L Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600